K080032

FEB 28 ...

SUMMARY AND CERTIFICATION

B. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for EnvoyCem.

SUBMITTER'S NAME:	Envoy Medical Corporation
ADDRESS:	5000 Township Parkway St. Paul, MN 55110
CONTACT PERSON:	Bernard (Bud) Horwath
TELEPHONE NUMBER:	651-361-8041
FAX NUMBER:	651-351-8001
DATE OF SUBMISSION:	28 December 2007

1. **Identification of device**
   Proprietary Name: EnvoyCem
   Common Name: Cement, Ear, Nose and Throat
   Classification Status: Class II per regulations 872.3275
   Product Codes: NEA

2. **Equivalent devices**
   Envoy Medical believes that EnvoyCem is substantially equivalent to the following devices:
   OTO-CEM, K011338
   SerenoCem, K003567
   OtoMimix, K042516

   EnvoyCem is glass ionomer cement as is OTO-CEM and SerenoCem and has essentially the same intended use as all three of the predicate devices.

3. **Description of the Device**
   EnvoyCem is glass ionomer cement that is provided as two components, a glass powder and polyalkenoic acid liquid. By mixing the two components, viscous moldable ionomeric cement is obtained which hardens in situ.

4. **Intended use**
   EnvoyCem is intended for use in otologic surgery for the following applications:
   - Augmentation or coupling of the middle ear ossicles.
   - Attachment of the middle ear ossicles to middle ear implants.
   - Mechanical stabilization of middle ear prostheses.

5. **Technological characteristics, comparison to predicate device.**
Like all the predicate devices, EnvoyCem is intended for use in various otologic surgical applications. EnvoyCem is glass ionomer cement as is OTO-CEM and SerenoCem. The following table provides a detailed comparison between EnvoyCem and the identified predicate devices.

Comparison table

Characteristic	**EnvoyCem**	**OTO-CEM**	**SerenoCem**	**OtoMimix**
Material	Glass Ionomer Cement (GIC)	Glass Ionomer Cement (GIC)	Glass Ionomer Cement (GIC)	Calcium Phosphate Cement (Hydroxyapatite-HA)
Indications for Use	Use in otologic surgery for 1. Augmentation or coupling of the middle ear ossicles 2. Attachment of the middle ear ossicles to middle ear implants 3. Mechanical stabilization of middle ear prostheses	Use in otological surgery for reconstruction of the ossicular chain.	Non-weight bearing applications in otologic surgery, such as: 1. The reconstruction of the ossicular chain where the cement can be used to repair bony ossicles in their normal position 2. Acoustic meatal wall construction in well-ventilated middle ears 3. Cementation of cochlear implants	Use in otologic surgery for 1. Augmentation or coupling of the middle ear ossicles 2. Attachment of the middle ear ossicles to middle ear implants 3. Mechanical stabilization of middle ear prostheses 4.Reconstruction of the posterior canal wall
Clinical Use	GIC has an extensive history of middle ear use	GIC has an extensive history of middle ear use	GIC has an extensive history of middle ear use	HA has a history of clinical use near dura, CSF
Biocompatibility	Non-cytotoxic per MEM Elution extract testing and shown to be equivalent to chemical composition of	Demonstrated biocompatibility per genotoxicity, acute oral toxicity, irritation, intramuscular implantation,	In vitro and in vivo clinical investigations have shown SerenoCem to be highly biocompatible	Demonstrated to be non-ototoxic

	OTO-CEM via chemical analysis testing using Fourier transform infrared spectroscopy.	subcutaneous implantation, intracutaneous reactivity, kinetics, pyrogen, skin sensitivity and cytoxicity.		
Use	Single use	Single use	Single use	Single use
Sterility	Provided sterile by Gamma Irradiation	Provided sterile by Gamma Irradiation	Provided sterile by Gamma Irradiation	Provided sterile by Gamma Irradiation
Packaging	0.5 gram capsule with proper ratio of liquid to powder	0.5 gram capsule with proper ratio of liquid to powder	Double foil pack around capsule	2 gram vials of powder and liquid
Accessories	Activator Applicator Mixer	Activator Applicator Mixer	Applicator Mixer	None (Hand Mixed)

6. **Discussion of performance testing.**
An extensive collection of tests has been conducted and successfully completed, including functional, accelerated shelf life, biocompatibility and sterilization validation. All testing indicates that EnvoyCem meets its specification requirements.

7. **Conclusion**
Based on extensive performance testing and a comparison to the predicate devices, it is the conclusion of Envoy Medical that EnvoyCem is substantially equivalent to devices already on the marked (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Envoy Medical Corporation
c/o Mr. Bernard Horwath
Regulatory Manager
5000 Township Parkway
Saint Paul, MN 55110

Re: K080032
Trade/Device Name: EnvoyCem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: NEA
Dated: January 4, 2008
Received: January 7, 2008

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE

510(k) Number K080032

Device Name: EnvoyCem

Indications for Use:

EnvoyCem is intended for use in otologic surgery for the following applications:

- Augmentation or coupling of the middle ear ossicles.
- Attachment of the middle ear ossicles to middle ear implants.
- Mechanical stabilization of middle ear prostheses.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K080032